84. (New) The device of Claim 30, wherein the blades are oriented approximately perpendicular to the sheet.

85. (New) The device of Claim 30, wherein the blades are oriented at an angle in the range of about 1° to about 89° to the sheet.

86. (New) The device of Claim 30, wherein the blades are oriented at an angle in the range of about 10° to about 60° to the sheet.

87. (New) The device of Claim 30, wherein the blades have a thickness in the range of about 7 μm to about 100 μm.

88. (New) The device of Claim 30, wherein the blades have a thickness in the range of about 25 μm to about 50 μm.

89. (New) The device of Claim 30, wherein the blades are composed of a material selected from the group consisting of metals, metal alloys, glasses, ceramics and rigid polymers.

90. (New) The device of Claim 30, wherein the sheet and the blades are substantially impermeable to the passage of the substance.

91. (New) The device of Claim 30, wherein the blades are thinner than the sheet.

REMARKS

Claims 6, 7, 30, 31, and 55-91 are pending in the application and under consideration. Claims 53-54 which were added in a Preliminary Amendment filed on August 24, 1998 were not addressed in the Office Action. These Claims correspond to Group I and are presumed to have been withdrawn from consideration by the Examiner.

Claims 6 and 30 have been amended. New Claims 55-91 have been added which depend from Claims 6 and 30.

Specification

The title of the invention has been amended to more clearly describe the invention to which the claims are directed. Further, the anchoring elements are mentioned in the title as requested in the Office Action.

Section 102 Rejection

The rejection of Claims 6, 7, 30, and 31 under 35 U.S.C. § 102(b) as being anticipated by *Gerstel, et al.* is respectfully traversed for the reasons stated herein.

The presently claimed invention is directed to a device used for transdermal delivery or sampling of an agent. One example of such a device is shown in FIG. 1 and includes a sheet 6 having at least one opening 8 and a plurality of blades 4 formed from the sheet and folded downward. At least one of the plurality of blades has an anchoring element for anchoring the device to a body surface. As shown in FIG. 2, the blades include an anchor which improves the attachment of the device to the skin so that the microblades are maintained in piercing relation to the outer layer of the skin (i.e., the stratum corneum). This ensures that the microslits cut through the stratum corneum are maintained continuously open while the device is worn on the skin, even during normal movement of the skin.

It is respectfully submitted that *Gerstel, et al.* fails to disclose key features of the combination of elements of the present Claims 6, 7, 30, and 31. *Gerstel, et al.* teaches a drug delivery device having projections 12 which permit a drug 20 to flow from a drug reservoir 39 to a body. The projections are generally at an angle of approximately 90° to the surface of the drug reservoir, but they can be disposed at any angle that will facilitate penetration of the stratum corneum. (Col. 7, lines 39-42) The present invention is distinguishable over *Gerstel, et al.* since *Gerstel, et al.* does not disclose any structure which operates as an anchoring element. While the angled projections of *Gerstel, et al.*

facilitate puncturing the skin, the projections, as taught, fail to prevent withdrawal of the device during movement of the body surface. Further, *Gerstel, et al.* does not teach or suggest that the angled projections function as an anchor. Rather the invention of *Gerstel, et al.* requires the use of a backing member with a peripheral adhesive (e.g., an adhesive overlay) for maintaining the device on the skin. (See column 6, lines 37-66) Accordingly, for at least these reasons, *Gerstel et al.* cannot anticipate Claims 6, 7, 30, and 31 of the present application.

The rejection of Claims 6, 7, 30, and 31 under 35 U.S.C. § 102(b) as being anticipated by *Ganderton, et al.* is respectfully traversed for the reasons stated herein.

Similarly, *Ganderton et al.* describes a dressing which delivers a pharmacologically active material from a reservoir 5 to a body using a plurality of individual fibers 4 that project from a permeable sheet 3. The fibers project from the sheet at an angle which achieve penetration of the skin, such as an angle of approximately 45°-90° to the face of the sheet. (See column 2, line 65 through column 3, line 2) A pressure bandage, adhesive tape, or an elasticated net retains the dressing in place. (See column 5, lines 26-44) *Ganderton, et al.* does not teach or suggest the use of an anchoring element on a portion of the blade as in the present invention. Accordingly, *Ganderton et al.* cannot anticipate Claims 6, 7, 30, and 31 of the present application for at least the same reasons discussed above with respect to *Gerstel, et al.*

Applicant has submitted new Claims 55-91 in order to more clearly claim the transdermal delivery or sampling device. Claims 55-91 correspond to original Claims 1-5, 10-29, and 34-45 and depend from pending Claims 6 and 30. No new matter has been added.

Conclusion

The Examiner mentioned that if the anchors were more carefully defined, it would be obvioius to combine the *Latterell, et al.* anchors with the *Gerstel, et al.* drug delivery device. This assertion is respectfully traversed for the reasons stated herein.

Latterell, et al. describes an electrocardial patch electrode 20 having an elongated conductor to which a plurality of dirk members (i.e., blades) 25 are connected. The dirk members may have terminal barbs 27 for anchoring the dirks in the myocardium. Applicant submits that one of ordinary skill in the art would not have been motivated to combine *Latterell, et al.* and *Gerstel, et al.* in order to achieve the purpose, function, and results of the present invention since *Latterell, et al.* fails to teach or suggest that the device could be used for drug delivery or sampling. Rather, *Latterell, et al.* teaches an electrode structure for which terminal barbs on the dirk members are used as an alternative to stitching the electrode in place. (Col. 3, lines 25-27) *Latterell, et al.* would not teach or suggest to one of ordinary skill in the art that terminal barbs should be used on the blades of a transdermal delivery or sampling device. Further, *Latterell, et al.* describes a device having removable dirk members to minimize damage to the heart tissue, whereas the present invention sufficiently pierces the body surface to create pathways through which a substance can be introduced or withdrawn.

In conclusion, Applicant respectfully submits that the cited references fail to teach or suggest the combination of features of the presently claimed invention. Therefore, it is respectfully submitted that all of the claims of the application are in condition for allowance which indication at an early date is respectfully solicited.

In the event that there are any questions concerning this response or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,

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